REMARKS

The Office action mailed May 12, 2003, has been received and its contents carefully noted. The pending claims, claims 16-47, were rejected. By this amendment, claim 16 has been amended to overcome the rejections. Claim 43 has been cancelled, without prejudice or disclaimer. New claim 48 has been added to specify one embodiment of the present invention. It is respectfully submitted that no new matter has been introduced by the amended and newly added claims. Support may be found in the specification and claim as originally filed. Reconsideration and entry of the amendment are respectfully requested.

Rejection Under 35 U.S.C. §112, first paragraph

The Examiner rejected claim 43 under 35 U.S.C. §112, first paragraph. The Examiner deemed that "fish oil" is not described or suggested in the specification as originally filed. Claim 43 has been cancelled, without prejudice or disclaimer. Therefore, the rejection under 35 U.S.C. §112, first paragraph should be withdrawn.

Rejections Under 35 U.S.C. §102(b)

The Examiner rejected claims 16-19, 21-39 and 42-47 under 35 U.S.C. §102(b) as allegedly being anticipated, or in the alternative, under 35 U.S.C. §103(a) as obvious over Haglund et al. (Nutritional Research, Vol. 13, pages 1341-1365, 1993), hereinafter Haglund.

Regarding the scops of the claims, Applicants respectfully submit that the claims as amended are limited by the phrase "consisting essentially of," which limits the claims to

elements that are necessarily present. Haglund describes the administration of folic acid with pyridoxine together with fish oils. B12 is not an ingredient of any formulation. There is no disclosure of co-administration of B12. There is also no disclosure of EPA or AA in Haglund. The present invention as amended requires at least one EFA, at least one homocysteine-lowering agent of vitamin B12, folic acid or vitamin B6 and optionally at least one antioxidant. The required elements in claims are different from those disclosed in Haglund. In particular, the claims as amended require specific daily doses of folic acid, vitamin B6 and/or B12, which are significantly different from those disclosed in Haglund. Haglund describes that the pyridoxine is administered at 80 mg per day and folic acid 10 mg per day, significantly higher than the doses required in the present invention. There is no disclosure in Haglund on the possible neurological and psychiatric toxicity of the high dose of B6 and folic acid which make them undesirable. Nowhere does the prior art teach or suggest the formulation and specific doses as claimed in the present invention. There is no suggestion that other doses might work or that B12 should be included in the formulation. Although on page 1361, paragraph 2 of Haglund there is a suggestion that the pyridoxine dose of 80 mg per day is rather high. The dose requirement is significantly lower than those in Haglund. Therefore, one of ordinary skill in the art would not be motivated to use the specific formulation and dose in the present invention with a reasonable likelihood of success.

Rejections Under 35 U.S.C. §103

Claims 16-19, 21-39 and 42-47 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over den Heijer et al. (Arterioscler. Thromb. Vasc. Biol. Vol. 18, 1998, pages

356-361) in combination with Horrobin (Prostaglandins Leukotr. Essential Fatty Acids, Vol. 53, 1995, pages 385-396) and Haglund et al. (Nutritional Research, Vol. 13, pages 1351-1365, 1993).

Horrobin discloses the use of EFAs for treatment of vascular disease. Den Heijer discloses that using vitamin B6, B12 or folic acid to lower homocysteine is desirable. Although Haglund discloses synergism when EFAs are administered with B vitamins, it uses a higher dosage. Therefore, Haglund does not provide motivation and suggestion to combine with Horrobin and den Heijer to achieve the present invention, in which the specific dose requirements are significantly different from prior art and lacking in prior art. Therefore, even if these references combined, they do not disclose the present invention. The "obvious to try" synergism in Horrobin is not sufficient to support the "obviousness" standard as required by 35 U.S.C. §103. It is respectfully submitted that the 35 U.S.C. §103 rejection be withdrawn.

Therefore, the invention as claimed is novel and nonobvious and the rejections under 35 U.S.C. §102(b) and 35 U.S.C. §103(a) should properly be withdrawn.

Extension of Time

A Petition for Extension of Time for one month under 37 C.F.R. §1.136 and the appropriate fee has been filed to extend the due date for responding to the Official Action to September 11, 2003.

Conclusion

Accordingly, in view of the foregoing amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of the claims to allow these claims and to find this application to be in allowable condition.

If the Examiner believes that a conference would be of value in expediting the prosecution of this application, the Examiner is invited to telephone the undersigned to arrange for such a conference.

Respectfully submitted,
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Date: September 11, 2003
Atty. Docket No. 1398/P65773US0
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